

REMARKS

The present application relates to inbred maize line PH6ME. Claims 2-44 and 47-49 have been canceled. New claims 50-79 have been added. No new matter has been added by the present amendment. Applicants respectfully request consideration of the following remarks.

Detailed Action

A. Claim and Specification Objections

Applicants acknowledge the objection of claims 8 and 27 as withdrawn. Applicants acknowledge the rejection of claims 1-49 under the judicially created doctrine of obviousness-type-double patenting as withdrawn. Applicants further acknowledge the rejection of claims 1-49 under 35 U.S.C. § 112, second paragraph, as withdrawn in light of the claim amendments. The rejection of claims 1-49 under 35 U.S.C. § 112, first paragraph, requiring a deposit of the seed of plant PH6ME, are acknowledged as withdrawn, in light of the deposit.

B. Newly Submitted Claims

Applicants acknowledge the addition of new claims 50 through 79, as specifically stated by the claims faxed by Examiner David Fox on November 15, 2002 and the new sample claim submitted by Supervisory Patent Examiner Amy Nelson via e-mail on August 7, 2003 and August 25, 2003. The new claims do not add new matter as there is support for the claims in the originally filed specification. Support for the specific items noted in the claims faxed by Examiner Fox can be found within the specification for *Bacillus thuringiensis* on page 28; for imidazolinone, sulfonylurea, glyphosate, glufosinate, L-phosphinothricin, triazine, and benzonitrile on pages 31-32; for phytase on page 32; for stearyl-ACP desaturase, fructosyltransferase, levansucrase, alpha-amylase, invertase and starch branching enzyme on pages 32-33; and for waxy starch and increased amylose starch on pages 21 and 33.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 3 and 22 are indefinite for the recitation "wherein said plant is manipulated to be male sterile". The Examiner states it is unclear if the claim is directed towards detasseled plants, or plants that have been transformed with a gene conferring male sterility.

Applicants have canceled claims 3 and 22 and added new claim 51 to include the language --detasseled--, as suggested by the Examiner, thus alleviating this rejection.

The Examiner rejects claims 5 and 24 for improper antecedent basis for "protoplasts" in line 1.

Applicants have now canceled claims 5 and 24, thereby alleviating this rejection.

Claims 12, 31, and 40 are indefinite for the recitation "comprising" in line 1 as the Examiner states it does not clearly indicate how many crosses are to be performed by the method.

Applicants have canceled claims 12, 31, and 40, alleviating this rejection.

The Examiner rejects claims 30 and 47 as indefinite for the recitation "essentially unchanged" as the Examiner states it is not clear what is meant by the term "essentially".

Applicants have canceled claims 30 and 47, thus alleviating this rejection.

Claim 33 stands rejected for the recitation "the pedigree of said maize plant is within 2 or less crosses" as being indefinite. The Examiner further states there is insufficient antecedent basis for "the pedigree".

Applicants have now canceled claim 33, thereby alleviating this rejection.

In light of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 9-14, 17-20, 28-33, 36-39, 41-44 and 47-49 remain and claims 15, 16, 34, 35, and 40 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed had possession of the claimed invention.

The Applicants traverse the rejection. Although not acceding to the Examiner's rejection, to expedite prosecution Applicants have canceled claims 2-44 and 47-49, thereby rendering this

rejection moot. Applicants have added new claims 50-79, as specifically stated by the claims faxed by Examiner David Fox on November 15, 2002 and the new sample claim submitted by Supervisory Patent Examiner Amy Nelson via e-mail on August 7, 2003 and August 25, 2003. The new claims do not add new matter as there is support for the claims in the originally filed specification as described *supra*.

Claims 18-20 and 47-49 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner further states it is not clear that single genes may be introgressed into the genetic background of a plant through traditional breeding. The Examiner also asserts that Hunsperger *et al.*, Kraft *et al.*, and Eshed *et al.* teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant.

Applicants respectfully traverse this rejection. The Applicants have provided assurance that at least 2500 seeds of inbred maize line PH6ME have been deposited with the ATCC. In view of this assurance, the rejection under 35 U.S.C. § 112, first paragraph, should be removed. (MPEP § 2411.02). Although not acceding to the Examiner's rejection, to expedite prosecution Applicants have canceled claims 18-20 and 47-49, thereby rendering this rejection moot. Applicants have added new claims 50-79, as disclosed *supra*. It is respectfully submitted that Applicants' claims are sufficiently described and enabled by the specification.

In addition, Applicants assert that the introgression of mutant genes and transgenes is easily, routinely and extensively practiced by those of ordinary skill in the art. Backcrossing has been known since the 1920's and, because of its predictability, is the method preferred by commercial plant breeders to introduce transgenes into already developed and tested material. An example of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the following:

is fully developed without undue experimentation.

Further, the Applicants would like to reiterate that a patent application "need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986); MPEP § 601.

Applicants also respectfully disagree with the Examiner as to what is taught by Hunsperger *et al.* Hunsperger *et al.* merely teaches that a gene that results in dwarfism of a petunia plant can be incorporated into other genetic backgrounds of the petunia species (See column 2, line 67 to column 3, lines 1-4). Hunsperger *et al.* merely discusses that the level of the expression of that gene differed in petunia plants of different genetic backgrounds. Hunsperger *et al.* succeeded in incorporating the gene into petunia plants of different genetic backgrounds. In fact, the USPTO in Hunsperger *et al.* allowed claims to any petunia plant comprising genes for dwarfism. Therefore, Hunsperger *et al.* supports the fact that one can introgress a specific trait into a recurrent parent through backcross conversion. Applicant's specification provides ample disclosure of starting materials such as, maize inbred line PH6.ME, a discussion of traditional breeding methods, and examples of transgenes and naturally occurring genes that may be used in such methods. Hallauer *et al.* (1988) on page 472, submitted in the Information Disclosure Statement, states that, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." The teaching of Hallauer *et al.* relates specifically to corn breeding and corn inbred line development.

The Examiner goes on to state that, "Kraft *et al.* teaches that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotypic specific and loci-dependent in nature" (page 323, column 1, lines 7-15). Applicants disagree that the article states such points. Kraft *et al.* makes no mention of a plant comprising a single gene conversion or the use of backcrossing. Further, Kraft *et al.* relates to linkage disequilibrium and fingerprinting in sugar beet, a crop other than maize. Kraft *et al.* states, on page 326, first column, "The generality of our results for other crop species needs to be investigated."

It is understood by those of skill in the art that backcrossing is a mutation technique, as the UPOV Convention's web site writes. The concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-

crossing and to fill the gap between Plant Breeder's Rights and patents." As determined by the UPOV Convention, "essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

The Examiner goes on to state that, "Eshed *et al.* teaches that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in genetically complex and less than additive fashion" (page 1815, column 1, line 1 to page 1816, column 1, line 1). The Applicants would like to point out on page 1816, column 1, lines 1-5 of the Eshed *et al.* article it states, "Recent studies that detected epistasis of selected QTL in *Drosophila* (Long *et al.* 1995), soybean (Lark *et al.* 1995) and maize (Doebley *et al.* 1995; Cockerham and Zeng 1996) did not show a less-than-additive trend." Emphasis added. Applicants also add that transferring a qualitative trait does not require undue experimentation. Please note Hallauer *et al.* (1988) on page 472, submitted in the Information Disclosure Statement, which states, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." Claims 2-44 ad 47-49 have been canceled to expedite prosecution. In claims 50-79, the genes transferred into PH6ME are now limited to the traits of disease resistance, insect resistance, herbicide resistance, male sterility, waxy starch, and a gene that encodes a product that modifies fatty acid metabolism, that decreases phytate content, or that modifies starch metabolism. Applicants respectfully request the Examiner to withdraw this rejection. For the reasons aforementioned, it is respectfully submitted that Applicants' claims are sufficiently described and enabled by the specification.

In light of the above amendments and remarks, Applicants respectfully request withdrawal of the rejections to claims 9-44 and 47-49 under 35 U.S.C. § 112, first paragraph.

Issues Under 35 U.S.C. § 102/103

Claims 9, 10, 13, 17, 28-30, 32, 33, 36, 41, 43, and 47-49 remain rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 102(a).

Applicants have canceled claims 2-44 ad 47-49 under 35 U.S.C. § 102(e), thereby alleviating this rejection. Applicants acknowledge the addition of new claims 50 through

79, as specifically stated by the claims faxed by Examiner David Fox on November 15, 2002 and the new sample claim submitted by Supervisory Patent Examiner Amy Nelson via e-mail on August 7, 2003 and August 25, 2003. The new claims do not add new matter as there is support for the claims in the originally filed specification. Further, Applicants submit *In re Thorpe*, states that "a product by process claim may be properly rejected over prior art teaching the same product produced by a different process", as noted by the Examiner. *In re Thorpe*, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). However, Applicants submit that this is not the same product physiologically or morphologically as the cited prior art as can be evidenced by one skilled in the art through analysis of the data tables in each. In addition, it is impermissible to use hindsight reconstruction and the benefit of Applicant's disclosure to pick among pieces which are present in the art; there must be some suggestion to make the combination and an expectation of success. *In re Vaeck*, 20 U.S.P.Q.2d 1434 (Fed. Cir. 1991). Moreover, Applicants claim a method of making a plant which did not previously exist. Pursuant to the recent Federal Circuit decision, *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research*, 304 F.3d 1221, (Fed. Cir. 2002), "a novel patented product is not 'anticipated' if it did not previously exist." *Id.* This is the case whether or not the process for making the new product is generally known. *Id.*

In light of the above, Applicants respectfully request the Examiner withdraw the rejection to claims 9, 10, 13, 17, 28-30, 32, 33, 36, 41, 43, and 47-49 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Noble, Jr. (U.S. Patent No. 6,118,056).

Summary

Applicants acknowledge that claims 1, 2, 4, 6-8, 21, 23, and 25-27 are allowed.

Applicants have amended the claims as suggested by Examiner David Fox and Supervisory Patent Examiner Amy Nelson as allowable. Applicants submit the claims place the application in condition for allowance and comply with all requirements of 35 U.S.C. § 101.

Conclusion

In conclusion, Applicants submit in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



Lila A. T. Akrad, Reg. No. 52,550
McKEE, VOORHEES & SEASE, P.L.C.
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309-2721
Phone No: (515) 288-3667
Fax No: (515) 288-1338
CUSTOMER NO: 27142

- mlw -

Attorneys of Record

FAX RECEIVED
AUG 27 2003
GROUP 1000

OFFICIAL